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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/967,274	09/27/2001	Joseph B. Richey II	12873/04169	6800
24024	7590	01/14/2004	EXAMINER	
CALFEE HALTER & GRISWOLD, LLP 800 SUPERIOR AVENUE SUITE 1400 CLEVELAND, OH 44114			EREZO, DARWIN P	
			ART UNIT	PAPER NUMBER
			3761	9
DATE MAILED: 01/14/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary**Application No.**

09/967,274

Applicant(s)

RICHEY, JOSEPH B.

Examiner

Darwin P. Erez

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*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 23 September 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-28 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-7, 10-17 and 19-28 is/are rejected.

7) Claim(s) 8,9 and 18 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) The translation of the foreign language provisional application has been received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____.

2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,155,257 to Lurie et al.
3. As to claim 1, Lurie teaches a method comprising the steps of sensing a carbon dioxide level (through module 122; col. 13. lines 42-49) associated with a patient breathing interface; determining if the level of carbon dioxide is increasing or decreasing; if the level is decreasing, determining if the level of carbon dioxide has crossed a threshold parameter; if the carbon dioxide level has crossed the threshold parameter, increasing the breathing gas pressure provided to the patient breathing interface; decreasing the breathing gas pressure provided to the patient breathing interface after a predetermined period of time (module 122 receives information from different sensors, including a carbon dioxide sensor, and controls the volume of gas supplied to the patient); and the increasing and decreasing of breathing gas pressure maintaining a positive pressure sufficient to sustain open the airway of a patient wearing

the breathing interface (col. 13, lines 53-55; the ventilator provides positive pressure to sustain open the airway of the patient)

4. As to claims 10, 17 and 21, the operation of the device of Lurie teaches the recited method steps because module 122 receives data from the sensors and compares it to a predetermined minimum and maximum values and controls the ventilator to maintain the actual value between the predetermined minimum and maximum values.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 2-4, 7, 11-13, 16, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lurie et al. in view of 6,099,481 to Daniels et al.

7. Lurie is silent with regards to the carbon dioxide sensor being an infrared sensor used within the patient breathing interface. Daniels teaches a sensor using infrared light within the patient breathing interface (col. 2, line 62; Fig. 1). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the sensor of Daniels in the step of detecting carbon dioxide of Lurie because it is known in the art to use different type of sensors to detect carbon dioxide levels,

including capnometers and infrared detectors, which would be available to of ordinary skill in the art.

8. Claims 5, 6 and 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lurie et al./Daniels et al. and in further view of US 5,193,544 to Jaffe.

9. Lurie/Daniels teaches all the limitations of the claims except for a fiber optic cable connected to the patient breathing interface. Jaffe teaches a carbon dioxide sensor wherein a fiber optic cable is used to emit **102** and sense **52** infrared light (col. 4, line 60). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the step of emitting and sensing the infrared light through a fiber optic cable because it is known in the art, as shown by Jaffe, to use a fiber optic cable in detecting carbon dioxide levels.

10. Claims 23 and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,954,050 to Christopher in view of US 5,193,544 to Jaffe.

11. As to claim 22, Christopher teaches a system for administering a breathing gas to a patient breathing interface comprising: a blower **40** for providing positive pressure breathing gas; a controller in circuit communication with the blower; a carbon dioxide sensor **87**; and a logic **60** capable of increasing and decreasing the level of the positive pressure breathing gas based on the level of carbon dioxide detected to maintain open the airway of a patient. Christopher is silent with regards to the carbon dioxide sensor comprising an infrared light emitter and detector in circuit communication with the

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controller for detecting the level of carbon dioxide associated with the patient breathing interface. Jaffe teaches a carbon dioxide sensor for use in respiratory device comprising an infrared light emitter **34** and detector **36**. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the carbon dioxide sensor of Jaffe in the device of Christopher because it provides a more accurate method of detecting carbon dioxide levels in the system.

12. As to claims 23 and 25-28, Christopher teaches a logic that synchronizes to the user's respiration based on a capnometer, therefore, inherently comparing the level of CO₂ (see col. 6, lines 35-67); Jaffe teaches the use of fiber optic cables **106**; Christopher teaches a carbon dioxide sensor within a housing accommodating the controller; and Jaffe teaches the carbon dioxide sensor located in the patient breathing interface.

13. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,954,050 to Christopher in view of US 5,193,544 to Jaffe and in further view of US 3,921,628 to Smythe et al.

14. The combination of Christopher/Jaffe is silent with regards to the system having a monostable timer. Smythe teaches a monostable timer in a ventilation system (see col. 7, lines 60-64). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the monostable timer of Smythe to the device of Christopher/Jaffe because it is known to have a monostable timer in a

ventilation system, as disclosed by Smythe, in order control the operation of the ventilator.

Allowable Subject Matter

15. Claims 8, 9 and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

16. Applicant's arguments with respect to claims 1-7, 10-17 and 19-21 have been considered but are moot in view of the new ground(s) of rejection.

17. Applicant's arguments filed 09/23/2003 have been fully considered but they are not persuasive. Applicant's arguments with regards to claims 22-28 is not persuasive because Christopher teaches a ventilator having a logic (computer) which is capable of performing the recited function. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezo whose telephone number is (703) 605-0420. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703) 308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.


GLENN K. DAWSON
PRIMARY EXAMINER

dpe